

## REMARKS

In the Office Action, claims 1-24 are rejected under 35 U.S.C. § 112, first paragraph; claims 1-24 are rejected under 35 U.S.C. § 112, second paragraph; and claims 1-24 are rejected under 35 U.S.C. § 103. Claims 1, 2, 7, 13, 19 and 24 have been amended. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for reasons set forth below.

In the Office Action, claims 1-24 are rejected under 35 U.S.C. § 112, first paragraph. The patent office alleges that the claim term "including" as claimed in claims 1, 7, 13, and 19 should be changed to "in the form of" in conformity with the specification. Although Applicants do not agree with this position, in the spirit of cooperation, Applicants have amended claims 1, 7, 13, and 19 as suggested by the examiner. In view of same, this rejection should be withdrawn.

In the Office Action, claims 1-24 are again rejected under 35 U.S.C. § 112, first paragraph. The patent office alleges that the claimed invention fails to satisfy the enablement requirement. Applicants believe that this rejection is improper.

Of the pending claims at issue, claims 1, 7, 13, and 19 are the sole independent claims. Claim 1 relates to a nutritional enteral composition intended for favoring the growth and maturation of a non-mature gastro-intestinal tracts of young mammals. The nutritional composition includes, in part, a mixture of dietary protein hydrolysates as claimed. Claim 7 relates to a method of preparing a nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals. The method includes, in part, using as a protein source a mixture of dietary protein hydrolysates as claimed.

Claim 13 relates to a method for providing nutrition to young mammals having non-mature gastro-intestinal tracts. The method includes, in part, administering a composition which contains as a protein source a mixture of dietary protein hydrolysates as claimed. Claim 19 relates to a method of promoting the growth and maturation of non-mature gastro-intestinal tracts of young mammals. The method includes, in part, administering a composition which contains as a protein source a mixture of dietary protein hydrolysates as claimed.

Contrary to the Patent Office's position, Applicants believe that the dietary protein hydrolysates claimed subject matter is clearly enabled as fully supported in the specification. For example, the specification provides that the dietary protein hydrolysates may be hydrolysates

of animal proteins (such as milk proteins, meat proteins and egg proteins), or vegetable proteins (such as soy proteins, wheat proteins, rice proteins, and peat proteins). The preferred source is milk protein where the dietary protein hydrolysates can be used as such or like peptide fractions isolated from them. See, Specifications, page 2, lines 4-10. Further, the specification provides that the dietary protein hydrolysates may be produced by using procedures which are well known in the art or may be obtained commercially. For example, nutritional formulas that contain hydrolysates with a degree of hydrolysis less than about 15% are commercially available from Nestle' Nutrition Company under the trademark Peptamen®; and hydrolysates that have a degree of hydrolysis above about 15% may be prepared by using the procedure described in European patents document No. 0322589. See, Specification, page 4, lines 31-36.

Moreover, the specification provides an example of a nutritional composition intended for specific gastro-intestinal maturation in premature mammals according to an embodiment of the present invention. The nutritional composition includes dietary protein hydrolysates, namely whey protein hydrolysates, that have been prepared according to the description in Example 1. See, Specification, pages 8-10. Applicants have discovered, for example, that hydrolysates with a degree of hydrolysis of about 15% to about 25% are found to increase the concentration of protein in the jejunum, the relative weight of the jejunum and the rate of protein synthesis in the jejunum. Further, highly hydrolysed protein with a degree of hydrolysis greater than 25% or which contains more than 25% by way of di- and tri-peptides, more preferably greater than 30%, are found to increase the rate of protein synthesis in the jejunum and the duodenum, particularly in the duodenum.

Based on at least these reasons, Applicants believe that one skilled in the art would be able to practice the claimed invention without undue experimentation. Therefore, Applicants believe that the claimed invention fully complies with 35 U.S.C. § 112, first paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-24 are rejected under 35 U.S.C. § 112, second paragraph. The patent office alleges that independent claims 1, 7, 13, and 19 and thus the remaining claims at issue which depend therefrom are rendered vague and indefinite by the phrase "dietary protein hydrolysates including a mixture of different size peptides and free amino acids," because the metes and bounds of the term "including" are not clearly delineated. As previously discussed,

Applicants have amended claims 1, 7, 13 and 19 to substitute the term “in the form of” for the claim term “including”. Further, Applicants believe that the claim term dietary protein hydrolysates is fully supported by the specification and thus clearly defined as previously discussed contrary to the patent office’s position. In view of the same, Applicants believe that the claimed invention fully complies with 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-24 are rejected under 25 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 4,977,137 (“*Nichols*”). The patent office alleges that Nichols discloses or suggests the claimed invention.

Applicants believe that this rejected is improper. As previously discussed, claims 1, 7, 13, and 19 are the sole independent claims that remain pending and at issue with respect to this rejection. Claim 1 relates to a nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals; claim 7 relates to a method of preparing a nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals; claim 13 relates to a method for providing nutrition to young mammals having non-mature gastro-intestinal tracts; and claim 19 relates to a method of promoting the growth and maturation of non-mature gastro-intestinal tracts of young mammals. Each of the independent claims recites a nutritional composition that includes a mixture of dietary protein hydrolysates and intact proteins. The dietary hydrolysates have a degree of hydrolysis that ranges from about 10% to less than 50% by weight and are in the form of a mixture of peptides and free amino acids wherein the free amino acids are present in an amount of up to about 20%. The intact proteins include, at least in part, bioactive proteins.

The nutritional compositions of the claimed invention provide very high nutrient needs for growth and development of non- or pre-mature gastro-intestinal tracts of young mammals. Further, the nutritional compositions as claimed can ensure optimal digestion and utilize (for tissue accretion) of the protein source and intends to minimize the nitrogen waste of the organism. Moreover, the protein mixture as claimed can provide a better source of amino acids to meet the general amino acid needs of the patient in addition to specifically favor maturation of individual organs. See, Specification, page 3, lines 4-10.

In particular, Applicants have discovered that the nutritional compositions with dietary protein hydrolysates that have a degree of hydrolysis of about 10% to about 15% can increase the relative weight of the liver as compared to free amino acid mixes. Further, hydrolysates with a degree of hydrolysis of about 15% to about 25% have been found to increase the concentration of protein, the relative weight, and the rate of protein synthesis in the jejunum as previously discussed. Moreover, with highly hydrolyzed dietary protein (e.g., degree of hydrolysis greater than 25% or which contains more than 25% by weight of di- and tri- peptides, more preferably more than 30%) has been found to increase the rate of protein synthesis in the jejunum and the duodenum, particularly the duodenum as previously discussed.

In contrast, Applicants believe that Nichols fails to disclose or suggest at least a number of features of the claimed invention. Indeed, Nichols merely discloses the addition of lactoferrin to a typical infant formulation or merely the consumption of lactoferrin on its own may promote the growth of gastro-intestinal tract in newborn mammals. Consequently, Nichols is directed to a particular bioactive molecule (lactoferrin) that can be used in an infant formulation.

This clearly contrasts the nutritional composition as claimed. The claimed nutritional composition includes a mixture of protein hydrolysates, free amino acids and intact proteins that provide desired and beneficial effects as previously discussed. For example, Applicants have discovered that the nutritional compositions with protein hydrolysates that have varying degrees of hydrolysis as claimed can promote the growth and maturation of non-mature gastro-intestinal tracts including the jejunum and duodenum in young mammals as previously discussed. In view of same, Applicants do not believe that one skilled in the art would be inclined to modify *Nicholas* to practice the claimed invention.

Based on at least these differences, Applicants believe that Nichols fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that Nichols fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

Applicants note for the record that claims 2 and 24 have been amended. No new matter has been added thereby. Applicants respectfully submit that the amendments were made for

clarification purposes and thus Applicants do not intend to narrow or disclaim any claimed subject matter in view of same.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of the same.

Respectfully submitted,

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